

**REMARKS**

Applicant acknowledges receipt of the Office Action dated March 21, 2008.

Reconsideration of the present application is respectfully requested.

**I. Status of the Claims**

Claims 1, 7, 8, 34 and 44-47 are amended, claims 2-6, 9, 10, 22-24, 27-28, 35, 39 and 42-43 are cancelled and claims 48 and 49 are added. Claim 1 is amended to recite embodiments previously recited in dependent claim 3. Claim 7 is amended to depend from claim 1. Claim 8 is amended to correct a minor typographical error. Claim 34 is amended to recite embodiments previously recited in dependent claim 42. Claims 44-47 previously depended from claim 34 and are rewritten in independent form. Claim 35 depended from claim 36, and has been cancelled and re-presented as new claim 48. Claim 49 recites embodiments previously recited in claim 1. Withdrawn claims 21, 25 and 38 are amended to conform to the amendments to claim 1.

None of the foregoing amendments introduce new matter, and their entry is respectfully requested. The foregoing amendments are made without prejudice or disclaimer, solely to advance prosecution, and not in acquiescence to any rejection. The right to pursue any cancelled subject matter in a continuing application is expressly reserved.

Following entry of these amendments, claims 1, 7, 8, 11-21, 25-26, 29-34, 36-38, 40, 41 and 44-49 will be pending. Claims 21-33, 38, 40 and 41 are withdrawn from consideration as non-elected method claims, and are subject to rejoinder pending allowance of the elected composition claims. Claims 1, 7, 8, 11-20, 34, 36-37 and 44-49 are presented for reconsideration.

**II. Claim Objections**

At page 10 of the Office Action, claims 8, 42 and 43 are objected to. The amendment to claim 8 overcomes the objection for misspelling "FSH." Claims 42 and 43 are canceled, obviating their objection.

### **III. Rejections Under 35 U.S.C. § 112, Second Paragraph**

At page 3 of the Office Action, claims 19, 20, and 36 were rejected under 35 U.S.C. § 112, second paragraph. Applicant respectfully traverses.

Claim 19 was rejected for allegedly lacking antecedent support for “the ratio of FSH to hCG.” Claim 19 depends from claim 1, which recites compositions with differing amounts of FSH and hCG. These compositions inherently have ratios of FSH to hCG. For example, claim 1 recites compositions comprising 50 IU FSH and 100 IU hCG, which has a FSH:hCG ratio of 1:2. Claim 1 also recites compositions comprising 50 IU FSH and 200 IU hCG, which has a FSH:hCG ratio of 1:4. Those skilled in the art readily will understand the ratio of FSH to hCG for each of the embodiments recited in claim 1. Thus, those skilled in the art readily will understand what is meant by “the ratio of FSH to hCG” as recited in claim 19. Accordingly, the claim is not indefinite and the §112 rejection should be withdrawn.

Claims 20 and 36 were rejected for allegedly failing to limit the previous claims because they “don’t specify the physical form of the instructions (e.g. a box with printing, a paper insert, a label).” Applicant respectfully traverses. Claims 20 and 36 further limit claims 19 and 34, respectively, by reciting that the assemblage or product further includes “instructions,” which are not required by claims 19 or 34. It is not necessary to specify the format of the instructions.

### **IV. Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description**

At page 3 of the Office Action, claim 44 was rejected because the recitation of “between 0.04 and 16  $\mu$ g” allegedly lacks support, even though the specification, in Figure 1B, shows compositions comprising 0.04, 0.2, 0.4, 1, 2, 3, 4, 8, 12, and 16  $\mu$ g hCG and 50, 75, 100, 150, or 200 IU FSH.

As MPEP § 2163 explains, “to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention” MPEP § 2163 (citing *Moba, B. V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 U.S.P.Q.2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1563, 19 U.S.P.Q.2d 1116

(Fed. Cir. 1991)). The “fundamental factual inquiry” for written description “is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.” *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-1564, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991)).

Importantly, “[t]he subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.” MPEP § 2163.02.

Here, the specification as filed adequately conveys Applicant’s possession of dosage forms comprising the range 0.04-16 µg. This is because the skilled artisan, seeing that Figure 1B reports compositions comprising 0.04, 0.2, 0.4, 1, 2, 3, 4, 8, 12, and 16 µg hCG and 50, 75, 100, 150, or 200 IU FSH, readily would understand that the range 0.04-16 µg hCG was part of the invention. Accordingly, the written description requirement of §112 is satisfied, and this rejection should be withdrawn.

## **V. Rejections Under 35 U.S.C. § 103**

At page 5 of the Office Action, claims 1-15, 19, 20, 34-37, and 43 were rejected under 35 U.S.C. § 103 as allegedly obvious in view of U.S. Patent 5,656,597 to Skrabanja *et al.* (“Skrabanja ‘597”) in view of WO 03/022303 to Menezo (“Menezo”). At page 7 of the Office Action, claims 1, 2, 11-20, 34-37, 46, and 47 were rejected under 35 U.S.C. § 103 as allegedly obvious in view of U.S. Patent 5,929,028 to Skrabanja (“Skrabanja ‘028”) in view of U.S. Publication 2004/0142887 to Cui *et al.* (“Cui”). As an initial matter, claims 2-6, 9, 10 and 35 are cancelled, rendering moot their rejection. Applicant respectfully traverses the rejection of the pending claims.

### **(i). Cui and Skrabanja ‘028 do not render obvious the pending claims**

The combination of Skrabanja ‘028 and Cui was cited against claims 1, 34, 36, 37, 46 and 47. Applicant respectfully traverses.

Cui was cited for teaching hCG. Cui does not teach hCG, however, but instead discloses formulations of hCG *antigen*, which is based on only 35-37 residues of the beta chain of hCG (the full chain has 145 amino acids). Cui administers this antigen as a

contraceptive vaccine, to induce antibodies against hCG to prevent pregnancy. *See Cui*, paragraph [0005].

*Cui* therefore is completely contrary to the present claims, which are directed to compositions comprising hCG useful, for example, to treat infertility and promote pregnancy. *Cui* therefore is not relevant to the patentability of the pending claims.

Skrabanja '028 discloses the administration of a wide range of doses of FSH and/or CG, ranging from 25 to 1500 IU FSH, and 15 to 10,000 IU hCG. *See Skrabanja '028*, col. 6, ll. 22-27. Skrabanja '028 does not teach or suggest the present invention, however, which recites compositions comprising specific amounts of FSH and hCG (claim 1 and its dependents), products comprising a composition comprising FSH and a composition comprising hCG, with specific  $\mu$ g amounts or concentrations of hCG and/or FSH (claim 34 and its dependents and claims 44-47), or a composition comprising an amount of FSH and hCG that is conducive, upon administration, to folliculogenesis and follicular maturation without ovarian hyperstimulation (claim 49).

The Office Action asserts that the claimed invention “merely recites the obvious employment of old and well-known ingredients” (Office Action at page 9), and seeks to foreclose further arguments against the obviousness rejection by citing to *Ex Parte Smith* USPQ2d, slip op. at 20, (Bd. Pat. App. & Interf., June 25, 2007):

Applicant is reminded that KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. Please see the recent Board decision *Ex parte Smith*, USPQ2d, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396). All of the elements parts in the instant composition are disclosed in Skrabanja et al.

Office Action at page 10. The citation to *Ex Parte Smith* is inaccurate, both as to the law under *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007), and to the facts.

In *Smith*, the Board concludes that a person of ordinary creativity could readily adapt the prior art to arrive at Smith’s technically simple invention. The Board’s statement that “KSR forecloses Appellant’s argument that a specific teaching is required to support a finding

of obviousness" (emphasis added) applied only to that Appellant, Smith, in the factual context of that case, and did not make a general pronouncement applicable to all obviousness rejections. To the contrary, in a decision applying *KSR*, the Federal Circuit emphasized that obviousness requires that the prior art give a reason or motivation to make the specific composition claimed. *Takeda Chem. Industs., Ltd. v. Alphapharm Pty, Ltd.*, 492 F.3d 1350, 1356 (2007). The *Takeda* decision is binding on the Patent Office, and confirms that, under *KSR*, the Patent Office still must point to some reason to modify the prior art in order to arrive at the claimed invention.

Here, the record provides no such reason. Skrabanja '028 does not disclose, or provide a reason or motivation to make, a single composition containing the specific amounts of FSH and hCG, as recited in claim 1 and its dependents, or a product comprising a composition comprising FSH and a composition comprising hCG, with specific  $\mu$ g amounts or concentrations of hCG and/or FSH, as recited in claim 34 and its dependents and claims 44-47, or a composition comprising an amount of FSH and hCG that is conducive, upon administration, to folliculogenesis and follicular maturation without ovarian hyperstimulation, as recited in claim 49. The Examiner cannot just overlook the specific recitations of the pending claims and cite *KSR* to establish obviousness. *KSR* did not do away with the requirement that, for a *prima facie* case of obviousness, the prior art must teach each aspect of the claimed invention.

Skrabanja '028 is concerned with specific means to improve delivery, rather than the amount of drug to be provided. Skrabanja '028 only describes specific doses of single drugs, and focuses on the use of longer-lasting versions of FSH (such as FSH-CTP). Thus, this reference is of little relevance to the pending claims.

Cui does not remedy the defects of Skrabanja '028 because the specific amounts taught by Cui pertain to hCG antigen, which, as explained above, is not hCG and is used for a completely opposite purpose than hCG.

Because the cited references do not teach or suggest the specific compositions and products recited in the claims, let alone indicate that such compositions could achieve the

results reported in the specification (and recited in the withdrawn method claims), the obviousness rejection based on Skrabanja '028 and Cui is improper and should be withdrawn.

**(ii). Skrabanja '597 and Menezo do not render obvious the claims**

The combination of Skrabanja '597 and Menezo was cited against claims 1, 7, 8, 11-15, 19, 20, 34, 35-37 and 43. Applicant respectfully traverses.

Skrabanja '597 is directed to gonadotrophin pharmaceutical compositions in lysospheres, which impart improved shelf life and recovery, and describes only single drug compositions of FSH or hCG. *See Skrabanja '597 at col. 1, ll. 16-22, col. 2, l. 10-col 3, l. 30.* Skrabanja '597 does not teach a single composition containing both FSH and hCG, as recited in claim 1 and its dependents and claim 49, let alone compositions comprising the amounts of FSH and hCG recited in claim 1.

Menezo is cited for disclosing a kit containing doses of hCG and FSH. However, Menezo does not describe co-administration of FSH and hCG in a single composition, as recited in claims 1 and 49, but instead teaches that hCG should be given several days *after* commencing FSH treatment. For example, Menezo, claim 1, and page 7, line 26 to page 9, line 3, makes clear that the claimed medicament includes hCG, and is separate from "FSH treatment" administered as part of COH.

Indeed, Menezo teaches away from providing FSH and hCG in a single composition.. For example, page 9, lines 4-9, of Menezo states that "administration of hCG should preferably not be started until at least 3 days after beginning FSH treatment . . . particularly preferably, administration of hCG should be started on or about the 7<sup>th</sup> or 8<sup>th</sup> day after commencement of FSH treatment." Thus, Menezo does not support the obviousness of claim 1 and its dependents or claim 49.

With regard to claim 34 and its dependents and claims 44-47, the Office Action does not make out a *prima facie* case of obviousness of these claims, which recite specific  $\mu$ g amounts or concentrations of FSH and/or hCG. As set forth above, the Examiner cannot ignore these claim limitations when evaluating the claims for obviousness.

Combining Skrabanja '597 and Menezo does not overcome the inadequacies of the references, as they both fail to teach or suggest compositions comprising both FSH and hCG as recited in claims 1 and 49, or compositions comprising the specific  $\mu$ g amounts or concentrations of FSH and/or hCG recited in claims 34 and 44-47. Because the cited references do not teach or suggest the specific compositions recited in the claims, let alone indicate that such compositions could achieve the results reported in the specification (and recited in the withdrawn method claims), the obviousness rejection based on Skrabanja '597 and Menezo is improper and should be withdrawn.

Claim 1 and its dependents are further distinguished from the cited references. Applicant has found that the administration of a single pharmaceutical composition consisting essentially of a combination of a specific amount of FSH and a specific amount of hCG, as recited in claim 1, may provide an effective medicament for, e.g., inducing ovulation. The efficacy of such compositions is shown in paragraphs [0060] to [0074] and Table 1 of the specification, which report significantly improved ovulation and pregnancy rates. Because nothing in the cited documents discloses or suggests the specific pharmaceutical compositions recited in claim 1, which include specific amounts of hCG (rather than LH) in combination with specific amounts of FSH, or indicates that such compositions might lead to significantly enhanced ovulatory induction effect, the obviousness rejection is improper and should be withdrawn.

**CONCLUSION**

Applicant believes that the application is in condition for allowance. An early notice to this effect is earnestly solicited.

If there are any questions regarding the application, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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